PARTICLE PHYSICS DIVISION ADMINISTRATIVE PROCEDURE
REVIEW AND APPROVAL RECORD

CALIBRATION POLICY & PROCEDURE FOR THE CONTROL OF MEASUREMENT & TEST EQUIPMENT

Revised by _____ /S007N_____ Date 4-10-2012
Rob Bushek

Approved by _____ Date 4/12/2012
PPD Head

1.0 PURPOSE:

This policy addresses the identification of PPD owned equipment considered to be controlled Measurement and Test Equipment (M&TE), and the requirements related to control and calibration of such equipment. M&TE is calibrated to ensure the accuracy and precision of data recorded and the decisions made based on that data. M&TE is controlled to maintain its suitability for use and its current calibration status.

This procedure meets requirements stated in DOE O 414.1C, the Fermilab Integrated Quality Assurance Plan and the Fermilab ES&H Manual.

2.0 SCOPE:

This policy does not apply to research apparatus/equipment unique to an experiment, which is set up and calibrated by researchers using procedures or processes which have been reviewed and accepted by the experiments appropriate scientific managers. Other equipment (e.g., oscilloscopes, multimeters, etc.) used in support of scientific research must be reviewed using this policy.

A graded approach is applied to M&TE control and calibration. M&TE needs to be calibrated only to the extent and intervals necessary to adequately perform the measurement involved. This ensures that emphasis is placed on equipment that has the greatest effect on personnel, safety and health, environment, data quality, cost, performance and schedule.
See the Graded Approach Procedure.
http://www.fnal.gov/directorate/OQBP/index/oqbp_active_procedures/Graded_Approach-Procedure_Rev%20000-1%20B10.pdf

There are two types of equipment that are considered critical and are required to follow this policy.

1.) Instrument subject to legal inspections (Law Regulation).
Example: MSA Altair 4-gas meters used for entering a permit required confined space.

2.) Other equipment used to provide accurate measurements that are vital to the integrity and credibility of the results.
Examples (but not limited to):
Scales, gages (micrometers, calipers, gage pins), oscilloscopes, Voltage / Ohms / Current/ Conductivity meters.

3.0 RESPONSIBILITIES:

3.1 Department Heads responsible for M&TE shall:

- Determine if calibration is required.
- Maintain a list of controlled M&TE. See Attachment #1
- Maintain calibration records necessary to substantiate results and processes of research, operational, or administrative activities to line management.

NOTE: Management authority may be delegated at the discretion of the Department head.

If PPD is using equipment owned by another division or institution it is the responsibility of PPD line management to ensure that the equipment meets the accuracy, precision, performance and safety requirements required for the task.

3.2 **Managers of organizations performing calibration operations** shall assure personnel performing these operations are properly trained and qualified, and this is documented in the Fermilab training database (TRAIN).

3.3 **All M&TE "owners" and users** shall properly store, handle and transport their equipment to assure its proper functioning and safety from damage and contamination.

4.0 PROCESS STEPS & EXPECTATIONS

4.1 Determining if Calibration is Required:

4.1.1 Equipment used in the following activities must be considered for calibration:

- Inspections;
- Acceptance testing;
- Data collection;
- Process monitoring;
- Maintenance, repair, and calibration of installed facility equipment and instruments.

4.1.2 In deciding whether to calibrate equipment identified for use in the above list of activities, consider the following:

- The Impact/Risk Level (See the Graded Approach Procedure).
- The level of designed redundancy built into the system for the monitoring/ testing performed. e.g., the use of two meters for the measurement.

4.1.3 Document the controlled M&TE and calibration requirements for the equipment including standards used. Attachment 1 is a possible format for recording relevant information. The format is usable either as hardcopy or electronic spreadsheet.

4.1.4 In situations in which most equipment does not require calibration, it is permissible to document only the equipment requiring calibration along with a statement that all other equipment is excluded from the calibration program.

4.2 Calibrating M&TE

The following general guidelines apply to equipment calibration whether done by Fermilab personnel or by an outside supplier of the service:
Calibrated equipment and reference standards should be calibrated in environments that will not adversely affect their accuracy. The following **environmental factors** should be considered as appropriate:

- Vibration
- Static Electricity
- Electromagnetic interference
- Background radiation

- Dust
- Cleanliness
- Fumes
- Temperature
- Humidity

The factors listed above should also be considered when calibrated equipment is being transported, used and stored.

Controlled M&TE shall be labeled with a PPD calibration label or an equivalent calibration label provided by an external calibration source. PPD Calibration labels are available from the PPD QAR or PPD/ES&H Department. Equipment that is not included in the calibration program should be labeled accordingly (i.e., "Not Calibrated" or "For Reference Use Only"), at the discretion of the cognizant manager.

Equipment shall be calibrated using calibration standards that are traceable to a recognized national or international standard, such as the National Institute of Standards and Technology (NIST). If no such standard exists, the basis for calibration shall be documented.

Calibration intervals shall be established based on legal requirements, manufacturer's recommendations, equipment usage, and/or prior calibration history. Calibration intervals shall be documented and maintained as a calibration record (see below).

Retired calibrated equipment should have its PPD calibration label removed and removed from the controlled equipment list.

Equipment that will be taken out of service for extended periods of time should be clearly marked as being out of service and that calibration is required before use.

Calibration records for each piece of controlled M&TE in the calibration program must be maintained in an "Equipment History File" which must also contain:

- Calibration frequency;
- Maintenance records;
- Reports of nonconformance involviug calibrated equipment;
- Calibration data and copies of calibration certificates.

The calibration procedures and the equipment calibration data should be reviewed annually to identify trends that may adversely impact measurements. Based on this review, questionable equipment may be retired or new equipment added, intervals of calibration may be adjusted, and procedures corrected.
All calibration records shall be maintained by the department that owns the equipment

Calibration by an Off-Site Supplier
Staff members who arrange for calibrations conducted by an off-site supplier shall locate a calibration service provider that is capable of calibrating your equipment. Acceptable calibration service providers include the original equipment manufacturer (OEM) or their calibration agency.

4.2.1 Calibration by a Fermilab Organization whether M&TE is calibrated by the owning organization or another Fermilab organization

4.2.1.1 Calibrate equipment in accordance with a written calibration procedure that is approved by the line manager, and as a minimum, includes the following information:

- Identity of the item to be calibrated;
- Calibration equipment and reference standards to be used;
- Checks, tests, measurements, and acceptance tolerances;
- Sequence of operations used to perform the calibration;
- Special instructions for calibration as necessary.
- Name of person or institution that performed calibration

Manufacturers' instructions, published standard practices, or other written instructions are acceptable if they contain the above information.

4.2.1.2 Document the calibration using an appropriate form that includes the following essential elements:

- Description;
- Manufacturer, Model Number, and the Serial Number or Unique Identification Number;
- Calibration procedure;
- Calibration frequency;
- Environmental conditions;
- Calibration technician or laboratory
- Comments;
- Standards and calibration equipment used (i.e., Description, Identification Number, and Calibration Due Date);
- Calibration data (i.e., Step, Function Tested, accuracy & precision Expected Plus/Minus Tolerance, and Before and After Data); and
- Performed by date and status (i.e., Accepted, Rejected, and Limitations).

Note: Attachment 2 offers a possible format for recording this information.

4.2.1.3 Label the equipment as follows:

- Verify that the equipment is clearly marked with its identification information (e.g., Model Number, and Serial Number or Unique Identification Number); and provide additional labeling if necessary.
- Due date of the next calibration or a label which states that the equipment's calibration must be up to date and the database should be checked before use.

NOTE: If the item is too small, a label can be affixed to its container. This label must include the equipment identification information.

4.2.1.4 Update all appropriate records in the Equipment History File.

4.3 Scheduling M&TE for Calibration

4.3.1 Identify controlled M&TE due for calibration and schedule calibration to enable return to use by the due date.

4.3.2 Perform appropriate follow-up on controlled equipment due for calibration that has not been found, i.e., equipment that may be lost or misplaced.

4.3.3 Calibrated controlled M&TE is tracked to ensure that it is calibrated on time. Tracking can be done by monitoring the calibration due dates either manually or using an electronic database.

4.3.4 If, because a piece of equipment is infrequently used, it is decided not to calibrate it according to its calibration schedule, then the user must ensure that the equipment is calibrated before it is used.

4.4 Control of M&TE

4.4.1 Storage or movement of portable M&TE between uses shall protect the equipment from damage, contamination and environmental factors. It is usually best to store the equipment in its supplied packaging if appropriate (e.g.; the wooden or plastic case in which micrometers are supplied).

4.4.2 Mounted or non-portable M&TE will be maintained between calibrations so as to protect it from damage, contamination and environmental factors to the extent possible. Should the M&TE become damaged, etc, it must be evaluated for suitability prior to continued use. If the M&TE is no longer suitable for use or the accuracy is in question, the damaged instrument must be repaired and calibrated or replaced.

4.4.3 M&TE found out of its calibration period shall be removed from use immediately, if possible. If removal is impractical (i.e., gauges) these are to be labeled with an "Out of Calibration" label. Under no circumstances should out of calibration equipment be used for measurements having Impact Levels of Serious or Important (See Graded Approach Procedure).

5.0 DEFINITIONS

Accuracy: The closeness of the agreement between the result of a measurement and the true value of the parameter being evaluated.

Calibration: The set of operations that establish, under certain specified conditions, the relationship between values indicated by a measuring instrument or system, or values represented by a material measure, and the corresponding known values of a parameter being evaluated.

Frequency: The time between successive scheduled calibrations for a given item or equipment.

Measurement and Test Equipment (M&TE): in general, equipment used to perform or determine inspections, acceptance testing, data collection, process monitoring, maintenance, repair, and calibration of installed facility equipment and instruments.

Out-of-tolerance: A condition in which a measured value of a measurement attribute lies outside the documented performance specifications for the attribute or a state in which one or more attributes of an item are not in conformance with documented performance specifications.

Precision: The ability to produce the same value or result, given the same input conditions and operating in the same environment.

Technical requirements: A list of the type of equipment, range, accuracy, tolerance, resolution, precision, and reliability to accomplish its intended function.

	TITLE:	MEASUREMENT AND TEST EQUIPMENT CONTROL AND CALIBRATION IDENTIFICATION ATTACHMENT 1
Department:		**DATE**

EQUIPMENT CALIBRATION INFORMATION

Description	Manufacturer	Model & Serial No. or Unique Id No.	Calibration Required	Calibration Frequency	Comments

		Calibration Documentation Attachment #2	
Department		**Date**	

Equipment Description		
Manufacturer		
Model No.	**Serial No.**	**Unique ID No.**
Calibration Procedure		
Calibration Frequency		
Comments:		

Environmental Conditions:		
Temperature:	**Pressure:**	**Relative Humidity:**

Standards and Calibration Equipment Used

Description	Identification No.	Calibration Due Date

Step	Function Tested	Expected +/- Tolerance	Before	After

Accepted ☐ **Rejected** ☐ **Limitations**

Next Calibration Due Date

Performed by Sign/Print: **Date**

Revision History

Author(s)	Description	Revision	Date
K. Schuh	Draft of New Policy		5/27/09
K. Schuh	Updated Draft based on comments received		7/08/09
R.Bushek	Updated example of instrument in 2.0(1) and some formatting throughout.	1	4/10/2012